IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION - COLUMBUS

UNITED STATES OF AMERICA Plaintiff vs. THOMAS ROMANO, Defendant	Case No. 2:19-cr-202 Judge Michael H. Watson

THE UNITED STATES' RENEWED MOTIONS *IN LIMINE*

The United States, by and through undersigned counsel, respectfully moves this Court for Orders *in limine* permitting the admission of: (1) evidence related to the overdose deaths of two of Defendant Thomas Romano, M.D.'s ("Dr. Romano") patients, and (2) data regarding Dr. Romano's controlled substance prescribing practices.

The United States refiles these Motions *in Limine* based on the Court's Order issued February 22, 2022 denying the government's motions without prejudice. (Doc. 52). In that Order, the Court outlined additional relevant factual and legal considerations pertaining to each Motion for the government to address. The United States addresses those issues below, and respectfully requests that the Court grant the government's Motions *in Limine*.

I. MOTION *IN LIMINE* TO PERMIT EVIDENCE RELATED TO OVERDOSE DEATHS OF DR. ROMANO'S PATIENTS

Evidence of the overdose deaths of two of Dr. Romano's patients should be admitted because it is intrinsic to the charged offense, it is relevant, and the high probative value of this evidence is not substantially outweighed by the danger of unfair prejudice. *See* Fed. R. Evid. 402, 403.

a. Factual Background

Dr. Romano began treating patient J.P. on December 11, 2015, for chronic pain related to prior motor vehicle accidents. Dr. Romano's medical records as to J.P. indicate that J.P. suffered from pain in his neck, shoulders, thighs, and lower back. Beginning with J.P.'s initial visit with Dr. Romano, Dr. Romano prescribed J.P. a powerful cocktail of the opioids oxycodone and oxymorphone.[1] Dr. Romano subsequently increased the dosage of these dangerous opioids in February 2016 and again in April 2016.[2] On September 16, 2016, Dr. Romano prescribed J.P. 30 milligrams of oxycodone to be taken five times a day.[3] The morphine milligram equivalent ("MME") for that oxycodone prescription was 225.[4]

According to a report generated by the Belmont County Coroner's Office and eyewitness accounts, during the early evening hours of September 17, 2016, emergency personnel responded to J.P.'s home in response to a call made by J.P.'s parents. Located at the scene was J.P.'s body, as well as money, marijuana, a white powdery substance, and an empty pill bottle for oxycodone prescribed by Dr. Romano, dated September 16, 2016. J.P.'s cause of death was later determined by the Belmont County Coroner's Office to be an overdose of oxycodone. A handwritten note in Dr. Romano's patient file for J.P., dated October 12, 2016, indicated that Dr. Romano had been

[1] The prescriptions provided by Dr. Romano on December 11, 2015, correspond with count 30 of the Superseding Indictment.
[2] The prescription provided by Dr. Romano on April 29, 2016, corresponds with count 31 of the Superseding Indictment.
[3] The prescription provided by Dr. Romano on September 16, 2016, corresponds with count 32 of the Superseding Indictment.
[4] MMEs are the amount of morphine an opioid dose is equal to when prescribed. A conversion to MMEs is often used as a gauge of the abuse and overdose potential that is being prescribed at one time to a patient. The Centers for Disease Control have directed that medical providers limit the MME dose they prescribe, as providers "should carefully reassess evidence of individual benefits and risks when considering increasing [an opioid] dosage" to any level greater than or equal to 50 MMEs per day and "should avoid increasing [a] dosage" of opioids greater than or equal to 90 MMEs per day without "carefully justif[ying]" such a decision. CDC Guideline for Prescribing Opioids for Chronic Pain, *available at* https://www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf (last visited February 16, 2022).

informed by another patient that J.P. died after falling in his apartment and breaking his neck. J.P. was 42 at the time of his death.

Dr. Romano began treating E.W. on February 23, 2016, for chronic pain related to prior motor vehicle accidents. Dr. Romano's medical records as to E.W. indicate that E.W. suffered from pain in his neck, the majority of the left side of his body, as well as his right hand and right ankle. Beginning with E.W.'s initial visit with Dr. Romano, Dr. Romano prescribed E.W. a powerful cocktail of controlled substances, including the opioids oxycodone and oxymorphone, as well as the benzodiazepine clonazepam and the muscle relaxer carisoprodol.[5] On April 19, 2017, Dr. Romano prescribed E.W. 30 milligrams of oxycodone to be taken ten times a day, 40 milligrams of oxymorphone to be taken twice a day, and 300 milligrams of the nerve pain medication gabapentin[6] to be taken six times a day.[7] The combined MMEs for the opioid medications prescribed by Dr. Romano to E.W. was 690. On April 27, 2017, E.W. refilled prescriptions from Dr. Romano for 1 milligram of clonazepam (to be taken twice a day) and 350 milligrams of carisoprodol (to be taken four times a day).[8]

During the early morning hours of May 9, 2017, E.W.'s wife, K.W., located an unconscious E.W. on the floor of their home. Emergency personnel was called to E.W.'s residence, but E.W. was later pronounced dead, at the age of 51. Located in E.W.'s bedroom was a plate, razor blade, snorting straw, and syringe. A white powdery residue was observed in E.W.'s nostrils. The State

[5] The prescriptions provided by Dr. Romano on February 23, 2016 correspond with count 26 of the Superseding Indictment. The government intends to introduce evidence at trial demonstrating that this combination of drugs that Dr. Romano prescribed—an opioid, a benzodiazepine, and a muscle relaxer—is referred to as the "Trinity" by drug seekers because of the potential "high" associated with that combination. When combined, the drugs are synergistic in causing respiratory depression and can collectively result in death.

[6] Gabapentin is not currently designated as a controlled substance by the State of Ohio or the Controlled Substance Act of 1970, although a number of states, such as Alabama, Kentucky, Michigan, North Dakota, Tennessee, Virginia and West Virginia, do classify it as such.

[7] The prescriptions provided by Dr. Romano on April 19, 2017 correspond with count 27 of the Superseding Indictment.

[8] The combination of drugs Dr. Romano distributed to E.W. in April of 2017 form the Trinity.

of West Virginia's Office of the Chief Medical Examiner ("OME") determined that E.W. died as a result of fentanyl and oxycodone intoxication. The OME's toxicology report indicated that E.W.'s blood contained fentanyl, norfentanyl, oxycodone, oxymorphone, and a marijuana metabolite. Dr. Romano's patient file for E.W. contained a handwritten note, dated May 24, 2017, that Dr. Romano was informed that E.W. had died.

Subsequent to the overdose deaths of patient J.P. in September 2016 and E.W. in May 2017, Dr. Romano failed to curb his over-prescribing of opioids and his dangerous practice of concurrently prescribing opioids with other controlled substances to patients, including to a number of the patients whose prescriptions form counts contained in the Superseding Indictment.

b. Argument

As an initial matter, evidence related to the patients' deaths is *res gestae* evidence, as it is inextricably linked to the charged offenses of 21 U.S.C. § 841(a), and the evidence will be offered to establish that the prescriptions which precipitated those deaths were unlawful, in that they were prescribed outside the usual course of professional practice and not for a legitimate medical purpose. *See United States v. Schwartz*, 702 F. App'x 748, 756 (10th Cir. 2017) ("[t]estimony regarding the deceased patients was inextricably connected to the charged offenses because it was offered to help prove that prescriptions written to those patients were unlawful and not consistent with accepted medical norms").

Moreover, evidence of patients' deaths can demonstrate a practitioner's "[w]anton disregard for the drug-abusive tendencies of its patients," establishing that the practitioner "knew that the clinic's patients were misusing their prescriptions, yet the practice continued to prescribe opioids in irresponsible ways." *Id*. "[T]he evidence of these patients' deaths could be considered by the jury when determining whether [the practitioner] knew that his patients were misusing his prescriptions. As we have said, this is one factor that may suggest that [the practitioner] distributed

controlled substances without a legitimate medical purpose and outside the usual course of professional practice." *United States v. Bourlier*, 518 F. App'x 848, 855 (11th Cir. 2013).

The matter before the Court is comparable to *United States v. Hofstetter*, 2019 U.S. Dist. LEXIS 211492 (E.D. Tenn. Dec. 9, 2019), which relied significantly upon *Schwartz* and *Bourlier*. In *Hofstetter*, the court determined that evidence of uncharged patients' deaths was admissible where it had a "[d]irect connection to a provider defendant, meaning the deceased patient was prescribed by a provider defendant and died shortly thereafter, often before their next appointment or within thirty (30) days." *Id*. at *15.

The *Hofstetter* court determined that "[e]vidence of such uncharged deaths is relevant and therefore admissible under Rule 402 of the Federal Rules of Evidence." *Id*. The court further found that "evidence of uncharged patient deaths has some tendency to suggest that a provider defendant knew or was deliberately ignorant of the fact that patients might be misusing prescriptions and overdosing." *Id*. (citations omitted). The *Hofstetter* court additionally found that the "[d]efendants' knowledge that patients were misusing prescriptions is 'one factor that may suggest that [the defendants] distributed controlled substances without a legitimate medical purpose outside the usual course of professional practice.'" *Id*. (citing *Bourlier*, 518 F. App'x at 855).

In its analysis pursuant to Fed. R. Crim. 403, the *Hofstetter* court determined that "[e]vidence of deaths of patients prescribed by a particular defendant is highly probative of that defendant's state of mind. . . . Evidence that defendants' patients were dying is probative of whether defendants knew or were deliberately ignorant of the fact that patients were not legitimate pain patients but were seeking pain pills and misusing their prescriptions. Moreover, because this particular category of evidence is defined by a direct and temporal connection between a particular

defendant's practice and a specific patient's death, the Court finds that this evidence is of exceptional probative value." *Id*. at *17 (internal citations omitted). As such, the *Hofstetter* court found that "[t]he high probative value of such evidence [was] not substantially outweighed by the danger of unfair prejudice." *Id*. at *18. Regarding any concerns as to unfair prejudice, the *Hofstetter* court determined that such concerns could be "[m]itigated to some extent by a limiting instruction." *Id*. at *19 (citing *Bourlier*, 518 F. App'x at 856; *see also Schwartz*, 702 F. App'x at 756).

Much like in *Hofstetter*, certain of Dr. Romano's patients overdosed and died, at least in part, as a result of the controlled substances Dr. Romano prescribed to those patients, and within a short time period after receiving the prescriptions.[9] There is also evidence in the patient files for J.P and E.W. that Dr. Romano was made aware of these patients' deaths shortly after they occurred. That evidence is highly probative as to whether Dr. Romano knew or was deliberately ignorant of the fact that his patients were not legitimate pain patients but were seeking pain pills and misusing their prescriptions, and whether the prescriptions were issued without a legitimate medical purpose and outside the usual course of professional practice. As such, the Court should permit evidence as to deaths of patient J.P. and E.W., as well as the circumstances surrounding their deaths.

In addition, evidence of the patients' deaths and the manner in which they occurred would disabuse the jury of any misconceptions as to the status and whereabouts of J.P. and E.W. Evidence as to the deaths of J.P. and E.W. would "[f]oreclose[] any idea that the patients stopped receiving prescriptions from [the practitioner] because [the practitioner] had stopped treating them." *Bourlier*, 518 F. App'x at 855. Furthermore, "[e]vidence of these patients' deaths would

[9] J.P. died the day after receiving a prescription for oxycodone from Dr. Romano; E.W. died 20 days after receiving prescriptions for oxycodone and oxymorphone from Dr. Romano.

have put to rest any idea that they were not called by the government to testify at trial because they only had good things to say about [the practitioner]." *Id*.

c. Government's Introduction of Evidence

In its February 22, 2022 Order, the Court instructed the United States to outline the manner in which it intends to introduce evidence regarding the overdose deaths of J.P. and E.W., as well as explain how the government plans to address hearsay and Confrontation Clause issues surrounding the admission of that evidence.

Regarding J.P., multiple witnesses will testify as to the circumstances of his death in Belmont County, Ohio. It is expected that Emergency Medical Technician Charli Gast ("EMT Gast") will testify regarding her response to the emergency call placed by J.P.'s parents, which requested emergency personnel respond to J.P.'s apartment in Belmont County. EMT Gast will further testify as to her contact with J.P.'s parents at J.P.'s apartment when she first arrived, as well as her futile efforts to assist J.P., who was deceased by the time she arrived at the scene. EMT Gast will also testify as to her observations of J.P.'s apartment, including the discovery of an empty medicine bottle. Subsequent to EMT Gast's arrival at J.P.'s apartment and her evaluation of J.P., she called Belmont County Coroner Investigator Timothy Skinner ("Investigator Skinner") and asked that he respond to the apartment to assist.

It is expected that Investigator Skinner will testify regarding his arrival at J.P.'s apartment, his evaluation of the deceased J.P., and observations he made regarding J.P.'s apartment, including locating an empty pill bottle labeled with J.P.'s name, the controlled substance oxycodone, and the date of September 16, 2016.[10] Investigator Skinner will further testify as to the blood draw he performed from J.P.'s heart, after Investigator Skinner spoke to Belmont County Coroner Troy

[10] Evidence presented during the course of the trial will establish that on September 16, 2016, Dr. Romano prescribed J.P. one hundred and fifty oxycodone 30 mg.

Balgo ("Dr. Balgo") regarding the case. Investigator Skinner will also testify as to the manner in which he marked the blood sample and the request he made for that sample to be tested. On September 23, 2016, Quest Diagnostics performed an analysis of the sample provided by Investigator Skinner and determined that the sample contained oxycodone and that it was negative for cocaine. On October 19, 2016, Dr. Balgo determined J.P.'s cause of death to be an oxycodone overdose.

Regarding E.W., multiple witnesses will testify as to the circumstances of his death in Wayne County, West Virginia. It is expected that K.W., E.W.'s widow, will testify that she woke up around 5:50 a.m. on the morning of May 9, 2017, in the home she shared with E.W. K.W. will testify that when she left the bedroom she observed E.W. to be laying on the floor. K.W. attempted to wake E.W. up and after realizing that he was non-responsive and cold to the touch, she immediately called 911 to seek help. K.W. will testify that she also called E.W.'s family, who lived nearby, to have them come help her resuscitate E.W. K.W. will testify that these attempts were futile as he was deceased when she found him. K.W. will testify that emergency personnel arrived shortly thereafter and secured the home.

It is expected that Wayne County Coroner Juanita Wilson ("Coroner Wilson") will testify regarding her response to the emergency call placed by K.W. Coroner Wilson will testify as to her arrival at E.W.'s home, her evaluation of the deceased E.W., and observations she made regarding E.W.'s home, including locating three pill bottles for medications Dr. Romano prescribed E.W. within 20 days of his death.[11] Coroner Wilson also found a plate, razor blade,

[11] Coroner Wilson will confirm that she found empty pill bottles for the controlled substances which previously contained 60 oxymorphone 40 mg pills (filled on April 28, 2017) and 120 carisoprodol 350 mg pills (filled on April 27, 2017). Coroner Wilson will further explain that she found a bottle for 180 pills of the non-controlled substance gabapentin 300 mg (filled on April 20, 2017), and that there were only three pills remaining. All three pill bottles reflected that E.W. received the prescriptions from Dr. Romano.

snorting straw, and syringe in the home, and found a white powder residue in E.W.'s nostril. Coroner Wilson will further testify that she secured E.W.'s body for transfer to the West Virginia Office of the Chief Medical Examiner in Charleston, West Virginia. Coroner Wilson will testify that after toxicological testing and the autopsy, E.W.'s death was pronounced as an overdose of his prescribed oxycodone and non-prescribed fentanyl on June 23, 2017.

This evidence is admissible because it is either non-hearsay, or constitutes a record of a regularly conducted business activity, *see* Fed. R. Evid. 801, 803(6), and because Dr. Romano has agreed to waive his Sixth Amendment right to confront the witnesses who authored the forensic lab reports and death certificates. First, these witnesses will be able to testify regarding the conditions of J.P.'s apartment and E.W.'s home, respectively, based on their first-hand knowledge and personal observations. These observations include confirming the individuals' deaths and the manner in which they were found, as well as important evidence such as the pill bottles and contraband that were found at each scene. Second, the parties have agreed by stipulation that the death investigation documentation, including the toxicology reports that resulted from both investigations, are records of regularly conducted business activity pursuant to Federal Rule of Evidence 803(6). These witnesses have direct knowledge of these reports and will be able to authenticate them as those produced as a result of the investigations, and as those maintained in the regular course of practice. Third, the parties have agreed by stipulation that these witnesses can be jointly classified as "key prosecution witnesses" for purposes of cross-examination on these topics.[12] *See Stevens v. Bordenkircher*, 746 F.2d 342, 347-8 (6th Cir. 1984); *see also Crawford v. Washington*, 541 U.S. 36, 61-3 (2004). While the government could subpoena both toxicology

[12] The government is careful to note that despite stipulating to the authenticity and regularly conducted business record nature of these documents, Dr. Romano is not stipulating to the relevance of this evidence under Fed. R. Evid. 401, nor ceding that the evidence is more probative than it is prejudicial under Fed. R. Evid. 403. Rather, the parties have stipulated solely that the evidence is authentic and qualifies as an exception to the hearsay rule under F.R.E. 803(6).

lab technicians that performed the blood sample testing, as well as Dr. Balgo on behalf of the Belmont County Coroner's Office and a representative of the West Virginia Office of the Chief Medical Examiner to confirm the final rulings on cause and manner of death for J.P. and E.W. respectively, counsel for Dr. Romano has agreed to waive any further requirement that the government present this additional testimony for purposes of the United States Constitution's Sixth Amendment Confrontation Clause.[13]

The United States respectfully requests that the Court admit evidence regarding the overdose deaths of J.P. and E.W. as extraordinarily relevant to the determination of whether Dr. Romano prescribed controlled substances to those patients outside the usual course of professional practice and without a legitimate medical purpose, and as strong probative evidence showing that Dr. Romano was aware of – or at least deliberately ignorant about – the danger in which he placed his patients through his prescribing practices, including those patients who received prescriptions from Dr. Romano similar to those J.P. and E.W. received, even after Dr. Romano became aware of J.P. and E.W.'s deaths.

II. MOTION IN LIMINE TO PERMIT CONTROLLED SUBSTANCE PRESCRIPTION DATA

Evidence of Dr. Romano's controlled substance prescription data across all patients, including for uncharged patients, during the relevant time period, is admissible to show intent, plan, and absence of mistake. *See* Fed. R. Evid. 404(b). This evidence is highly probative of Dr. Romano's intent and whether he issued the charged prescriptions outside the usual course of professional practice and without a legitimate medical purpose, and is not substantially outweighed by the danger of unfair prejudice. *See* Fed. R. Evid. 403.

[13] As outlined above, this stipulation extends only to a Confrontation Clause review of this evidence, and the parties agree that Dr. Romano is not ceding any arguments to the admission of this evidence based on objections to its relevance or undue prejudice pursuant to Fed. R. Evid. 401 or 403.

a. Factual Background

The government plans to call Paul Short ("Mr. Short"), a representative of Drug Enforcement Administration ("DEA") Document and Media Exploitation ("DOMEX") division. Mr. Short is the Unit Chief for the DOMEX Office of Special Intelligence, and he has served in that position since June 2012. In this capacity Mr. Short supervises teams of intelligence analysts who review and analyze documents and electronic media, including the analysis of pharmacy records, patient files, and prescription drug monitoring program ("PDMP") reports. Prior to becoming the Unit Chief for the DOMEX Office of Special Intelligence, Mr. Short served as an intelligence analyst and supervisory intelligence analyst for the National Drug Intelligence Center of the United States Department of Justice. From 2000 to 2012, Mr. Short supported approximately 200 drugs investigations as an Intelligence Analyst.

Mr. Short reviewed Dr. Romano's PDMP data from the states of Ohio, West Virginia, Pennsylvania, and Indiana. Mr. Short will testify as to the existence of PDMP databases throughout those states, as well as the state laws which require pharmacies operating in those states to report all fills and re-fills of controlled substances in Schedules II through IV. The states require pharmacies to submit accurate data, with that data being compiled and maintained in a central and searchable database. Mr. Short will also testify that these databases allow medical practitioners to check if their patients are receiving controlled substance prescriptions from other doctors, which is a red flag that a patient is an addict or is selling their medication. Mr. Short will testify that these databases are allow accessible to administrative and regulatory agencies, as well as the law enforcement, to maintain oversight of medical practitioners' prescribing practices. Mr. Short will explain that this type of oversight is commonplace, and that the DEA employs multiple divisions to review prescribing practices for potential abuse and diversion of prescription medication. Mr.

Short will explain that in his position, he is aware of multiple "red flags" of prescribing practices, including but not limited to a prescriber issuing prescriptions for: 1) high doses of controlled substances; 2) dangerous combinations of controlled substances; and 3) patients who travel long distances to a particular doctor from whom they are receiving controlled substance prescriptions.

In addition to the background information on PDMPs generally, Mr. Short will testify as to his statistical and analytical review of Dr. Romano's prescribing practices from January 1, 2015 to June 28, 2019. Mr. Short will testify that Dr. Romano exhibited multiple red flags through his prescribing practices during this time period. Among those findings, Mr. Short will explain that Dr. Romano's PDMP records reflect opioids accounted for over 76% of all controlled substances he prescribed, with oxycodone constituting 55% of the total prescribed substances. Further, Dr. Romano's PDMP shows that he prescribed incredibly high doses of opioids – between three and ten times the highest dose recommended by the Centers for Disease Control for safe and effective opioid therapy – to up to 21% of his patient population. Mr. Short's analytical review also uncovered that Dr. Romano prescribed dangerous combinations of controlled substances to his patients routinely. Specifically, Dr. Romano prescribed combinations of opioids and benzodiazepines, which the United States Food and Drug Administration identified in 2016 created a tenfold higher risk of overdose death among patients when compared to those prescribed opioids alone, to 170 of his 304 patients. Moreover, Mr. Short found that Dr. Romano prescribed the "Trinity" – a dangerous combination of an opioid, benzodiazepine, and muscle relaxant – to 31 of his 304 prescribed patients during this period.[14] Mr. Short also identified that the vast majority of

[14] This finding is particularly noteworthy for multiple reasons. The "Trinity" is known for its addictive tendency to increase euphoric effects when taken together. For that same reason, the "Trinity" is also known as an increased risk of abuse and potential overdose, as well as for street-level drug diversion. Finally, this analytical finding is corroborative of the findings of the government's medical expert, Dr. Timothy Munzing, M.D., who will testify as to the medical risks of this type of concurrent prescribing. Dr. Munzing will specifically testify that Dr. Romano's "Trinity" prescribing to patients T.M., M.R., J.T., P.T., and E.W. was outside the usual course of professional practice

the patients paid for prescriptions with insurance coverage (commercial, Medicaid, Medicare, and/or Worker's Compensation).[15] Mr. Short has prepared summary exhibits detailing his findings, which will aid the jury in understanding the nature of these red flags identified in the Dr. Romano's prescribing practices.

Mr. Short's testimony about his analytical review of prescribing practices and PDMP analysis has been admitted in approximately 16 federal criminal proceedings, including in the 2021 case of the *United States v. Samson Orusa* in the United States District Court for the Middle District of Tennessee.[16]

b. Argument

Within the confines of Fed. R. Evid. 404(b), the PDMP data is admissible to show Dr. Romano's intent, his plan or scheme to issue prescriptions without a legitimate medical purpose, and the absence of mistake. "Uncharged prescriptions of controlled substances in enormous quantities, and in dangerous combinations, support a reasonable inference that the underlying prescriptions were issued outside the usual course of professional practice and without a legitimate medical practice. [The practitioner's] practice-wide evidence was therefore probative of his unlawful intent, undermining his defense at trial that the charged prescriptions amounted to 'a few bad judgments.'" *United States v. Lague*, 971 F.3d 1032, 1040 (9th Cir. 2020); *see United States v. Noel*, 2021 U.S. App. LEXIS 33416, *9-10 (6th Cir. 2021) (red flags such as prescriptions written for and filled by out-of-state patients, non-insurance payments at inflated prices, high doses of opioids, and patients traveling long distances to fill prescriptions support a reasonable inference

and was without a legitimate medical purpose based on his review of the patients' individual circumstances and his medical knowledge, training, and experience.

[15] This finding is noteworthy because Dr. Romano ran a cash-only medical practice, charging patients approximately $100 - $200 per month or more for their office visits regardless of whether they maintained medical insurance.

[16] 3:18-cr-00342-1, United States District Court for the Middle District of Tennessee (Nashville).

the underlying prescriptions were filled outside the usual course of professional practice);[17] *United States v. Kraynak*, 2021 U.S. Dist. LEXIS 149559, *12-13 (M.D. Pa. Aug. 10, 2021) (PDMP evidence allowed the jury to evaluate the practitioner's prescribing practices as a whole and compare those practices to other physicians within the state, which was important for the jury in evaluating whether the prescriptions were appropriate, or whether they were excessive and outside the usual course of professional practice and without a legitimate medical purpose).

Indeed, the jury "may consider prescription data sets outside those specifically charged in the indictment to determine whether a physician has exceeded 'the legitimate bounds of medical practice' and 'as evidence of a plan, design, or scheme.'" *United States v. Merrill*, 513 F.3d 1293, 1302 (11th Cir. 2008) (citation omitted); *United States v. Katz*, 445 F.3d 1023, 1029 (8th Cir. 2006) (uncharged prescriptions were relevant and admissible under 404(b) as proof of knowledge and intent); *United States v. Stump*, 735 F.2d 273, 275 (7th Cir. 1984) (evidence of large number of prescriptions written by defendant but not charged in the indictment were admissible under 404(b) as proof of intent); *United States v. Harrison*, 651 F.2d 353, 355 (5th Cir. 1981) (in considering whether the defendant exceeded legitimate medical practice, "[p]rescriptions issued at other times were admissible as evidence of plan, design or scheme"). The broader data is essential to show that Dr. Romano was not, for example, deceived by manipulative patients in the charged counts that simply fooled him into over-prescribing controlled substances, or that he just made a few bad judgments.

Instead, much like in comparable circumstances in *Lague* and *Kraynak*, Dr. Romano's PDMP data is probative of Dr. Romano's unlawful intent and whether the prescriptions issued

[17] Mr. Short was the testifying witness for these analytical findings in the United States' case-in-chief against Dr. Lague. *See United States v. David Lague*, 4:2017-cr-00150, United States District Court for the North District of California. Mr. Short's testimony was the subject of the Ninth Circuit Court of Appeals' findings upholding the admission of this type of evidence.

were excessive and therefore outside the usual course of professional practice and without a legitimate medical purpose, outweighing any danger of unfair prejudice to Dr. Romano. The PDMP data is damaging to Dr. Romano, but only if the jury believes that it represents evidence of intent. If the jury does not accept that assertion, then the data will not be damaging to Dr. Romano in any capacity. The PDMP data contains statistics, which are not in themselves inflammatory and will not tend to incite the jury's passion. Regardless, any concerns as to the PDMP data having an unfairly prejudicial impact upon the jury can be addressed via appropriate jury instructions. *See Kraynak*, 2021 U.S. Dist. LEXIS 149559 at *23; *Noel*, 2021 U.S. App. LEXIS at *6-7.

Further, the PDMP data upon which Mr. Short relied upon in making his analytical findings are regularly conducted business records which are subject to the hearsay exception outlined in Federal Rule of Evidence 803(6). As a threshold matter, the parties in this case have agreed by stipulation that the PDMP data Mr. Short relied upon in reviewing Dr. Romano's prescribing practices are authentic and constitute regularly conducted business records pursuant to Federal Rule of Evidence 803(6).[18] This stipulation is consistent with other courts' treatment of substantially similar PDMP data. In *United States v. Ruan*, the Eleventh Circuit Court of Appeals directly and thoroughly addressed the admissibility of PDMP data. *United States v. Ruan*, 966 F.3d 1101 (11th Cir. 2020).[19] In *Ruan*, the district court admitted PDMP data of defendant doctors Xiulu Ruan and John Patrick Couch over defense objections, including on grounds that the evidence was inadmissible hearsay. The Eleventh Circuit Court of Appeals noted that the defense was offering a three-prong objection to hearsay in the PDMP records: 1) hearsay in the

[18] As with prior stipulations, the parties agree that Dr. Romano's stipulation to the authenticity and regularly conducted business record nature of the proffered PDMP evidence does not foreclose argument on the relevance or prejudicial effect of the evidence under Federal Rule of Evidence 401 and 403 respectively.

[19] Mr. Short was the testifying witness for these analytical findings in the United States' case-in-chief against Dr. Ruan and Dr. Couch. *See United States v. Couch*, et.al.,1:2015-cr-00088, United States District Court for the Southern District of Alabama. Mr. Short's testimony was the subject of the Ninth Circuit Court of Appeals' findings upholding the admission of this type of evidence

prescriptions, the information from which is input into the PDMP system; 2) hearsay as to the information about the prescriptions that the dispensing pharmacists put into the PDMP database, and 3) the reports that PDMP users can create from the data. I. at 1150-1. The *Ruan* court, however, dispatched each of these arguments. First, the Eleventh Circuit found that the prescriptions themselves were not hearsay because they constitute an opposing party's statements under Federal Rule of Evidence 801(d)(2)(D) and (E). *Id.* The Eleventh Circuit then found that compilations of otherwise-admissible evidence does not itself constitute hearsay, so PDMP database reports are not *per se* hearsay. *Id*. (internal citations omitted). Third and most notably, the Eleventh Circuit found that that PDMP reports are "comprised records of regularly conducted activity made by persons with knowledge whose job duties entailed making those records…" *Id.* PDMP records are by state and federal regulation updated at the time pharmacists fill prescriptions, fulfilling both of the requirements under Federal Rule of Evidence 803(6) that the records be made regularly and at or near the time by – or from information transmitted by – someone with knowledge of the prescriptions. *Id.* The *Ruan* court thereby found that, as to the second level of purported hearsay – the pharmacist's inputting of the data – the PDMP documentation was admissible under the Federal Rule 803(6) exception to hearsay as a regularly conducted business document. *Id.*

The Sixth Circuit Court of Appeals has made substantially similar findings about the admissibility of other pharmacy records, including by affirming a trial court's admission of pharmacy purchase logs over a hearsay objection because they were documents that were kept in the ordinary course of business. *See United States v. Hillis*, 656 Fed.Appx. 222, 226-27 (6th Cir. 2016). Many courts, including District Courts in the Southern District of Ohio, have admitted PDMP data at trial without objection. *See United States v. Saad Sakkal,* 1:18-cr-088 (jury trial

before the Honorable Judge Michael R. Barrett in which PDMP data was admitted); *United States v. Nicole Georges*, 2:20-cr-00157 (jury trial before the Honorable Chief Judge Algenon L. Marbley in which PDMP data was admitted after stipulation by the parties).

The United States respectfully requests that the Court admit evidence of Dr. Romano's prescribing practices as captured through PDMPs for the dates outlined above and allow Mr. Short to testify regarding his analytical review thereof, to aid the jury in understanding the scope of Dr. Romano's dangerous prescribing and to support a finding that the prescriptions outlined in the Superseding Indictment were issued outside the usual course of professional practice and without a legitimate medical purpose.

CONCLUSION

For the foregoing reasons, this Court should grant the government's motions *in limine* and permit evidence of the death of J.P. and E.W. during the trial in this case, as well Dr. Romano's prescribing data and the analytical review thereof performed by Mr. Short.

Respectfully Submitted,

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/s/Andrew B. Barras
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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 24th day of February, 2022, I filed the foregoing United States' Motions *in Limine* with the Clerk of Court, and that a true and accurate copy of the foregoing was forwarded via ECF to the Defendant's counsel of record.

By: *s/Andrew Barras*

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